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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,885	06/22/2001	Hirokazu Matsumoto	55999(46342)	7940

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EXAMINER	
BASI, NIRMAL SINGH	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,885	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3, 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/9/01.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Response to restriction requirement filed 11/03/03 has been entered.

Election/Restriction

Applicant's election without traverse of Group I, claims 1-3 and 6-10 on 11/3/03 is acknowledged. Claims 4-5 withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

2. **Objections**

The disclosure is objected to because of the following informalities:

The specification, page 56, lines 9 and 17, refers to a compound obtained in "Example 21", which was subsequently dissolved in water, the specification does not contain an Example 21. Clarification is needed. It appears "Example 21" should have been "Example 2". Applicant is requested to amend the typographical error, if one has occurred or disclose where in the specification Example 21 can be found.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-3 and 6-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3 and 6-7 recite a oxytocin secretion regulator or oxytocin secretion but do not recite that they are isolated or purified. The claims, as currently recited, encompass these naturally-occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "an isolated and purified" to overcome this rejection.

Claim 8 and 9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Amending the claim to recite "a process or a method" will obviate this rejection.

Claim Rejection, 35 U.S.C. 112

4. Claims 1-3, 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the name oxytocin secretion regulator does not provide any structural limitations and the metes and bounds of the claim cannot be determined. It is unclear what structure encompasses oxytocin secretion regulator. It is suggested, to overcome the rejection, oxytocin secretion regulator be identified by SEQ ID NO.

The term " substantially" in claim 2 is a relative terms which renders the claim indefinite. The term "substantially" is not clearly defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear when an amino acid sequence is substantially the same as compared to it not being substantially the same so as to allow the metes and bounds of the claim to be determined.

Claim 6 is indefinite because the names oxytocin secretion regulator and oxytocin secretion promoter do not provide any structural limitations and the metes and bounds of the claim cannot be determined. It is unclear what structure encompasses oxytocin secretion regulator and oxytocin secretion promoter. It is suggested, to overcome the rejection, oxytocin secretion regulator and oxytocin secretion promoter be identified by SEQ ID NO.

Claim 7 recites the limitation " oxytocin secretion stimulator according to claim 6". There is insufficient antecedent basis for this limitation in the claim. Claim 6 recites an "oxytocin secretion regulator" and "oxytocin secretion promoter". Further it is unclear what are "uterine inertia, atonic hemorrhage, placental expulsion, subinvolution or lacteal retension" . The specification does not provide a definition of the terms "uterine inertia, atonic hemorrhage, placental expulsion, subinvolution or lacteal retension", so as to allow the metes and bounds of the claim to be determined. To over come the rejection Applicant can disclose where in the specification said terms are defined or

provide prior art disclosing the art accepted meaning of said terms so as to allow the metes and bounds of the claim to be determined.

Claims 8 and 9 provides for the use of a ligand peptide, or salt thereof, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved.

Claim 10 is indefinite because it is not clear when a disease is related to insufficient oxytocin secretion so as to allow the metes and bounds of the claims to be determined. Specifically, when is a disease considered related and what levels of oxytocin are considered insufficient?

Claim 3 is rejected for depending upon an indefinite base (or intermediate) claim and fail to resolve the issues raised above.

Claim Rejection, 35 U.S.C. 112

5. Claims 1, 2, 3, 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified oxytocin secretion regulator, comprising a ligand peptide which has the amino acid sequence represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, or a salt thereof, for G protein-coupled receptors phGR3 and UHR-1, does not reasonably provide enablement for other oxytocin secretion regulators. The, specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the person of ordinary skill in the art would, in light of the specification be able to isolate oxytocin secretion regulator, comprising a ligand peptide which has the amino acid sequence represented by SEQ ID NO:3, SEQ ID NO:18, SEQ ID NO:32 and SEQ ID NO:44, or a salt thereof, for G protein-coupled receptors phGR3 and UHR-1, the scope of the claims, which encompass other ligand peptides which may be structurally and functionally different to the ligand amino acid sequence represented by SEQ ID NO:3, SEQ ID NO:18, SEQ ID NO:32 and SEQ ID NO:44 are not enabled by the disclosure. The claim encompasses ligands that bind to other undisclosed G protein coupled receptors. The claims encompasses ligands, organic and inorganic compounds, which may be completely unrelated to the peptides represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44. Prior art discloses three preproteins from bovine, rat and human (see IDS Ref CC, page 273, Figure 2) containing prolactin-releasing polypeptides (PrRP), which are represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 in instant specification. SEQ ID NO: 44 is a generic sequence which encompasses all the variable mutations which may act as functional PrRP and interact with hGR3 or UHR-1 to regulate prolactin release and oxytocin release (see IDS Ref CC and CA). The specification and prior art has disclosed a specific genus of polypeptides, which interacts with a specific G protein-coupled receptor to elicit a specific response. The critical feature required for activity is contained in the PrRP polypeptides encompassed by SEQ ID NO:3, SEQ ID NO:18,

SEQ ID NO:32 and SEQ ID NO:44. There is no disclosure of other compounds, inorganic or organic, which contain the critical feature of the invention, which can be used to isolate and purify, claimed invention. The disclosure does not teach how to isolate, make and purify ligands other than those represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44 which interact with other unknown G protein coupled receptors and have oxytocin secretion regulator functions without undue experimentation. Further claims 1, 6 and 7 do not disclose the critical feature of the invention, which is required for structure and function. The specification does not disclose a single inorganic molecule, which meets the limitations of the claims, although inorganic molecules are encompassed. Further, structurally deficient polypeptides, containing random mutations, interacting with unrelated G protein-coupled receptors would not be expected by the skilled artisan to result in oxytocin release. Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for a functional oxytocin secretion regulator, and with which specific G protein coupled receptor it binds, except those as indicated as enabling above, would prevent the skilled artisan from making, isolating and purifying a ligands for a G protein-coupled receptor which retains oxytocin secretion regulator function of the instant invention. Further, oxytocin secretion regulators, apart from those represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, are not enabled for use in regulation of oxytocin release or for manufacture of an oxytocin secretion regulator, for reasons given above.

Due to the large quantity of experimentation necessary to identify and purify active oxytocin secretion regulators, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said polypeptides, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of oxytocin secretion regulator, are also encompassed by the claim), and the breadth of the claim which fail to recite functional limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

Claim Rejection, 35 U.S.C. 112

6. Claims 7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not reasonably provide enablement for use of an oxytocin secretion stimulator for treatment of a disease related to insufficient oxytocin secretion or for ameliorating, preventing or treating uterine inertia, atonic hemorrhage, placental expulsion, subinvolution, cesarean section, induced abortion or lacteal retention.

Claims 7 and 10 encompass methods of treatment. The claims provide no structural limitations on the oxytocin secretion regulator. The specification provides no correlation between the diseases being treated and the oxytocin secretion regulator used for said treatment. The specification discloses the concentration of oxytocin, in

blood, was two times higher than controls, five minutes after administration of 10nmol of PrRP to the third ventricle. There is no nexus between administration of PrRP and oxytocin levels in blood to treatment of a disease related to insufficient oxytocin secretion or for ameliorating, preventing or treating uterine inertia, atonic hemorrhage, placental expulsion, subinvolution, cesarean section, induced abortion or lacteal retention. Further Maruyama discloses (IDS ref. CA) the plasma levels of both oxytocin and vasopressin did not change when PrRP was administered intravenously (page 195, column 2, second paragraph). There is no disclosure of any disease state related to PrRP dysfunction. There is no disclosure of how an increase or decrease in oxytocin levels, as a result of administration of oxytocin secretion regulator, will affect a particular disease state. Is increase in oxytocin secretion beneficial or detrimental? Is a decrease in oxytocin secretion beneficial or detrimental? As stated in the specification, page 57, the ligand peptides in the present invention may result in desensitization of the receptor proteins. There is no disclosure how the disease state will be affected by desensitization. The specification has not provided even a single case of a disease state that can be treated with administration of the oxytocin secretion regulator. Further the oxytocin secretion regulator cannot prevent uterine inertia, atonic hemorrhage, placental expulsion, subinvolution, cesarean section, induced abortion or lacteal retention. For example, how can the administration of oxytocin secretion regulator prevent cesarean section or induced abortion? Cesarean section or induced abortion can be physical actions, which can occur regardless of the concentration of oxytocin secretion regulator.

Accordingly, the instant specification provides insufficient guidance on "how to use" the oxytocin secretion stimulator/regulator for treatment of a disease related to insufficient oxytocin secretion or for ameliorating, preventing or treating uterine inertia, atonic hemorrhage, placental expulsion, subinvolution, cesarean section, induced abortion or lacteal retention.

In order to practice the invention one of skill in the art would have to identify compounds that regulate oxytocin secretion, identify disease states that can be regulated by oxytocin secretion stimulator/regulator and determine modes of administration that would effect oxytocin levels. However, the specification does not disclose the nexus between the disease states and oxytocin secretion stimulator/regulator, claims do not define the oxytocin secretion stimulator/regulator. The specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim without undue experimentation. Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands (8 USPQ2d 1400 (CA FC 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented. The claims encompass treatment of a disease. Neither the specification nor the prior art provide sufficient guidance as to what specific diseases could be treated by administering the undisclosed oxytocin secretion regulator/stimulator claimed. Attempting to identify a disease treatable by such a " regulator/stimulator would

constitute undue experimentation. Therefore one of skill in art would have to identify a disease treatable by said regulator/stimulator, determine effective compositions, determine effective doses to achieve the intended purpose, determine routes of effective administration, determine if the oxytocin secretion regulator/stimulator can reach its target tissue without degradation and determine if it has a therapeutic effect, all of which would constitute undue experimentation Therefore, the unpredictability to achieve all the afore mentioned goals and the lack of guidance provided in the specification, the disclosure fails to enable one of skill in the art how to make and/or use the oxytocin secretion regulator/stimulator encompassed by claims 7 and 10.

7. Claims 1-2, 6-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims are drawn to:

a) Oxytocin secretion regulator/promoter, comprising a ligand peptide or a salt thereof, for G protein-coupled receptor protein

b) Oxytocin secretion regulator, of a) which is the same or substantially the same as the amino acid sequence represented by SEQ ID NO: 44

c) Methods of use of a) and b)

The specification discloses an oxytocin secretion regulator, comprising a ligand peptide which has the amino acid sequence represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, or a salt thereof, for G protein-coupled receptors phGR3 and UHR-1. The scope of the claims, encompass other ligand peptides which may be structurally and functionally different to the ligand amino acid sequence represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44. The claim encompasses ligands that bind to other undisclosed G protein coupled receptors. Prior art discloses three preproteins from bovine, rat and human (see IDS Ref CC, page 273, Figure 2) containing prolactin-releasing polypeptides (PrRP), which are represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 in instant specification. SEQ ID NO: 44 is a generic sequence which encompasses all the variable mutations which may act as functional PrRP and interact with hGR3 or UHR-1 to regulate prolactin release and oxytocin release (see IDS Ref CC and CA). The specification and prior art has disclosed a specific genus of polypeptides, which interacts with a specific G protein-coupled receptor to elicit a specific response. The critical feature required for activity is contained in the PrRP polypeptides encompassed by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44. There is no disclosure of other compounds, which contain the critical feature of the invention, which can be used to isolate and purify claimed invention. The disclosure does not teach how to isolate, make and purify ligands other than those represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44 which interact with other unknown G

protein coupled receptors and have oxytocin secretion regulator functions without undue experimentation. Further claims 1, 6 and 7 do not disclose the critical feature of the invention, which is required for structure and function. Further, structurally deficient polypeptides, containing random mutations, interacting with unrelated G protein-coupled receptors would not be expected by the skilled artisan to result in oxytocin release. Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for a functional oxytocin secretion regulator, and with which specific G protein coupled receptor it binds, except those as indicated as enabling above, would prevent the skilled artisan from making, isolating and purifying a ligands for a G protein-coupled receptor which retains oxytocin secretion regulator function of the instant invention. Further, oxytocin secretion regulators, apart from those represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, are not enabled for use in regulation of oxytocin release or for manufacture of an oxytocin secretion regulator, for reasons given above.

The instant disclosure of one distinct polypeptide, SEQ ID NO: 44, encompassing SEQ ID Nos: 3, 18 and 32 does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, fusion polypeptides and variants thereof; and compositions comprising said polypeptides. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by an amino acid sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a

substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The fusion polypeptides, fragments and variants encompassed by the claims do not disclose the critical technical feature of the claimed invention or its relationship to function. It is not clear what critical technical feature the undisclosed oxytocin secretion regulator provide so as to show a written description of the invention in full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing. The specification proposes to discover other members of the genus by using hybridization techniques. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. One of skill in the art would reasonably conclude that the

disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

An adequate written description of a protein, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of a protein is more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the protein itself. Accordingly, the specification does not provide a written description of the invention of claims 1-2, 6-10.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6 and 8-9 rejected under 35 U.S.C. 102(b) as being anticipated by Takeda Chemical Industries Ltd. (Ref A). Takeda Chemical Industries Ltd. disclose an oxytocin secretion regulator, comprising a ligand peptide, or salt therof, for a G-protein-coupled receptor protein (inherent property of oxytocin secretion regulator), which has 100% sequence identity to SEQ ID NO:3, 18, 32 and 44 of instant application (see claim 2). Takeda Chemical Industries Ltd also disclose the use of a ligand peptide or salt thereof, for a G-protein-coupled receptor protein (inherent property of oxytocin secretion regulator), for manufacture of an oxytocin secretion regulator (see claim 9). The disclosure of Takeda Chemical Industries Ltd meets the limitations of Claims 1-3 and 8-9, absent evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 703-308-9435. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Nirmal S. Basi
Art Unit 1646
1/12/04

MICHAEL PAK
PRIMARY EXAMINER